REMARKS

Claims 1-12 and 31-42 are currently pending, and have been rejected in the outstanding office action. Reconsideration is requested.

Applicant wishes to acknowledge the courtesies extended by Examiner Yabut during the telephone interview held December 19, 2007. The Interview Summary mailed by the Examiner on December 27, 2007, accurately reflects the substance of the interview, including the prior art to Gambale and Redmond that was discussed in view of claim 1. Applicant argued that Gambale has no removable septum, and by making the suggested modification to add a removable septum to Gambale renders the device inoperable because the folds of tissue in the Gambale device would unfold without the septum being present. The foregoing is believed to substantially represent the discussions had during the interview.

Claims 1-12 and 31-42 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gambale (U.S. Pub. No. 20030208209) in view of Redmond (US Pat. No. 6,334,865). Applicant respectfully traverses the rejection for the reasons discussed below.

Examiner states that Gambale does not disclose a septum being removable from between the first and second openings, as recited in claim 1, or first and second ports, as recited in claim 31, and that Gambale does not disclose the septum being adapted for abrading adjacent tissue. Further, Examiner states that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to provide a removable septum, as taught by Redmond, to Gambale in order to facilitate treating the tissue separately." Applicant respectfully traverses the rejection for the reasons set forth below.

With all due respect, the Examiner has not provided the reasons why a person of ordinary skill in the art would have combined the prior art elements in the manner

claimed. KSR Intern. Co. v. Teleflex, Inc., 127 S. Ct. 1727, 1742 (2007). To facilitate review, "this analysis should be made explicit." See Memorandum, May 3, 2007, from Margret A. Focarino, Deputy Commissioner for Patent Operations to Technology Center Directors. A *prima facie* case of obviousness cannot be made absent the proper analysis.

Further, Redmond does not disclose a removable septum, but instead discloses a semi-permiable barrier that can be deployed to block hemostatic material within a tissue track and allow blood from a vessel to flow into the tissue track to mix with the hemostatic material. The Examiner states that Redmond "teaches a septum ('barrier assembly') 4G, longitudinally positionable in a slot or common channel of the tissue positioning device, being removable from between first and second openings (Figures 14-16; col. 8, line 57 to col. 9, line 14)."

However, it appears that the Examiner has misinterpreted Redmond, which discloses a percutaneous tissue track closure assembly that includes a semi-permeable barrier 26 mounted to the distal end of a tubular barrier carrier 20. As shown in FIGS. 14 through 14B, the barrier assembly 4G includes an inner tube 78 and an outer tube 76 with slits 80, 82 at their distal ends between the tip 84 and the stop ring 86. See Redmond col. 8, lines 29-41. By pulling on a barrier actuator 22G, both tubes 76, 78 buckle in the region of the slits 80, 82, causing arms 88, 90 to buckle into a deployed configuration shown in FIGS. 14B. See Redmond col. 8, lines 41-50. There are also a number of fluid-flow-permitting gaps 91 created by the expanding arms 88, 90 that are small enough to prevent flow of hemostatic flowable material 30 there through but large enough to permit passage of blood into tissue track 12 for interaction with material 30. See Redmond FIG. 4B and col. 8, lines 50-56.

Redmond does not describe or suggest a removable septum positionable in a slot or common channel of a tissue position device that is removable between first and second openings. For these reasons, the cited references do not teach a removable septum as

recited in independent claims 1 or 31, and since all of the claim limitations are not taught or suggested, claims 1-12 and 31-42 are patentable over Gambale in view of Redmond.

The 35 U.S.C. § 103(a) rejection of the pending claims should also be withdrawn, since the combination of references is improper and the device of Gambale would not work for the intended purpose if it were combined with a removable septum or the barrier of Redmond. With reference to FIGS. 40 and 41 and paragraph [0171], the Gambale device operates by drawing two tissue portions 890 into two separate vacuum chambers 860. The vacuum chambers are formed within the device such that a portion of the external surface 852 divides the two chambers. To place a suture through the two folds of tissue, a needle 880 passes through a channel 894 and through the double folds of tissue acquired by the device. See paragraphs [0171] and [0172] of Gambale. Therefore, the exterior surface 852, which the Examiner refers to as a septum, does not need to be removable to allow a fastener to be deployed to secure the first area of tissue to the second area of tissue, because there is a channel 894 that provides a passage way for the needle 880 to pass through to secure the dual folds of tissue.

Gambale contains no teaching, suggestion, or motivation to replace or modify the suturing method using the needle 880 passing through channel 894 as shown in FIG. 40, with the hemostatic material barrier of Redmond. The only possible motivation for combining Redmond with Gambale came from Applicant's own disclosure, which is impermissible use of hindsight. Therefore, there is no motivation or suggestion found in either Gambale or Redmond to combine a hemostatic material barrier with the Gambale device.

In a telephone interview with the Examiner on August 1, 2007, Examiner agreed with counsel for Applicant that there is no motivation or suggestion in Gambale to remove the septum of the device for the following reasons previously stated in Applicant's response filed august 6, 2007. Removing the septum 852 would defeat the intended purpose of Gambale, which is to "secure multiple tissue portions 52

simultaneously for application of a tissue securing device, such as a suture, tag or staple." See paragraph [099] of Gambale. As discussed in Gambale, the advantage of the Gambale device over the prior art is that it secures "two tissue portions 52 in the same number of steps that the prior art device requires to secure a single tissue portion." Id. If the septum 852 is removed while the tissue is acquired, the acquisition of two folds of tissue would be lost and only one fold would remain to be secured. Therefore, the Gambale device combined with a removable septum would eliminate the intended purpose of Gambale, to acquire and secure multiple folds of tissue together simultaneously. This is an impermissible combination of references under M.P.E.P. § 2143.01. In other words, Gambale teaches away from having a removable septum as recited in independent claims 1 and 31, because the device in Gambale requires a stationary septum 852 to separate the vacuum chambers 860 and create two folds of tissue to be secured together. Accordingly, claims 1-12 and 31-42 are patentable over Gambale in view of Redmond.

In view of the foregoing, Applicant respectfully submits that all pending claims are now in condition for allowance. Reexamination and reconsideration of the application are respectfully requested and allowance at an early date is solicited.

The Commissioner is authorized to charge deposit account no. 06-2425 for any unforeseen fees arising from the filing of this paper.

Respectfully submitted,

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